

SAIBER SCHLESINGER SATZ & GOLDSTEIN, LLC

ATTORNEYS AT LAW

ONE GATEWAY CENTER
13TH FLOOR
NEWARK, NEW JERSEY 07102-5311
TELEPHONE (973) 622-3333
TELECOPIER (973) 622-3349
WWW.SAIBER.COM

BRUCE I. GOLDSTEIN⁺
WILLIAM F. MADERER⁺
DAVID J. D'ALOIA^{*}
JEFFREY W. LORELL^{*}
DAVID R. GROSS^{*}
SEAN R. KELLY⁺
ARNOLD B. CALMANN^{*}
STEPHEN H. KNEE^{*}
JOAN M. SCHWAB
JENNINE DISOMMA^{*}
JAMES H. FORTE
VINCENT F. PAPALIA
RANDI SCHILLINGER⁺
MICHAEL J. GERAGHTY^{*}
NINO A. COVIELLO^{*}
MICHELLE V. FLEISHMAN^{*}
AGNES I. RYMER^{*}
JAMES H. GIANNINOTO^{*}
NANCY A. WASHINGTON
ERNEST E. BADWAY^{*}
MARC C. SINGER⁺
SETH E. ZUCKERMAN
MARC E. WOLIN⁺
DAVID A. COHEN

SAMUEL S. SAIBER
1929-2002

GEOFFREY GAULKIN
ALFRED M. WOLIN
SPECIAL COUNSEL

DAVID M. SATZ, JR.
NORMAN E. SCHLESINGER
MORTON GOLDFEIN^{*}
DAVID J. SATZ
HEIDI WEGRYN GROSS
OF COUNSEL

ROBERT B. NUSSBAUM
COUNSEL

^{*} MEMBER OF NJ & NY BARS
⁺ MEMBER OF NJ & PA BARS
⁺ CERTIFIED BY THE SUPREME
COURT OF NEW JERSEY AS A
CIVIL AND CRIMINAL TRIAL
ATTORNEY
^{*} CERTIFIED BY THE SUPREME
COURT OF NEW JERSEY AS A
CIVIL TRIAL ATTORNEY

JEREMY P. KLEIMAN^{*}
JEFFREY SOOS
TONI MARIE VACCARINO^{*}
DANALYNN T. COLAO^{*}
MELISSA A. PROVOST
CHRISTINA L. FICHERA^{*}
CHRISTOPHER M. WOLFE
JENNIFER R. O'CONNOR
HOPE M. LLOYD^{*}
ANTHONY DEL GUERCIO^{*}
PAOLA CIAPPINA HEMSLEY
DANIELLE PANTALEO^{*}
JONATHAN D. LEVY⁺
PHOEBE S. SORIAL^{*}
DEBORAH D'ANGELO
MELISSA A. SILVER
COLIN R. ROBINSON⁺
PARIS DASKALAKIS^{*}
DANIELE N. HANKIN^{*}
DENNIS KADIAN^{*}
JONATHAN M. BUSCH
HILLARY A. JURY⁺
ERIKA SONDAHL LEVIN
BRYAN P. SCHROEDER⁺
ANDREW D. LA FIURA
LAUREN M. LIMAURO
GEORGE TENREIRO

September 1, 2005

VIA ELECTRONIC FILE AND HAND DELIVERY

Honorable John J. Hughes, U.S.M.J.
United States District Court, Room 5000
Clarkson S. Fisher Federal Building
and United States Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *Shire Laboratories Inc. v. Nostrum Pharmaceuticals, Inc.*
Civil Action No. 03-4436 (MLC)

Dear Judge Hughes:

We, along with our co-counsel Edgar H. Haug, Steven M. Amundson, and Sandra Kuzmich, Frommer Lawrence & Haug, LLP, represent plaintiff Shire Laboratories Inc. ("Shire") in this patent infringement action against defendant Nostrum Pharmaceuticals, Inc. ("Nostrum"). In accordance with Your Honor's direction during the August 17th conference call with the Court, and pursuant to Federal Rule of Civil Procedure 16(b) and District of New Jersey Local Civil Rule 16.1(f) and (g), we respectfully move this Court to modify the Scheduling Order to allow the submission of limited supplement expert reports.

As demonstrated below, substantial good cause exists to support the modest modification of the Scheduling Order. The interests of justice favor allowing the requested additional discrete expert discovery, and no prejudice will accrue to Nostrum from the requested modification. Further, such a modification results in no delay of the scheduling of a *Markman* hearing or trial. The proposed additional expert information

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will assist the trier of fact by ensuring the development of a thorough and complete record that will enable the Court to reach a just and proper decision in this case.

For at least the following reasons, Shire respectfully requests that the Court grant its motion to amend the Scheduling Order to permit the introduction of limited supplement expert reports.

A. THE NOVEMBER 16, 2004 STATUS CONFERENCE

Throughout the course of this case Shire has consistently taken the position that expert discovery is essential to understanding the technology surrounding the patent in suit and identifying the key issues pertaining to the question of infringement. By contrast, Nostrum's position has been just the opposite—expert discovery is not needed for resolution of this case. At this juncture, it has become clear that expert opinions and testimony will be instrumental in assisting the Court in determining the meaning of claim terms and resolving the question of infringement.

On November 16, 2004, Your Honor held a Status Conference during which expert discovery was discussed and scheduled. It was at that conference that the parties' contrary views on expert discovery were first articulated. While Shire argued that expert discovery is an essential part of the record that is needed prior to the filing of summary judgment motions, Nostrum argued just the opposite. Nostrum contended that resolution of the issues (i.e., claim construction and infringement) did not require expert discovery. In fact, Nostrum requested that this Court stay expert discovery until its summary judgment motion was decided—a request that was denied by Your Honor. The schedule ultimately entered as a result of the November 16th Status Conference incorporated a parallel track of summary judgment motion briefing and submission of expert reports. *See* Order dated December 14, 2005 (**Exhibit 1**).

At the November 16th Status Conference the timing of expert depositions was also considered. While expert depositions *would be permitted* following the exchange of expert reports, neither party *would be required* to take depositions prior to an April 27, 2005 Status Conference. *See id.* at 2 (emphasis added). The flexibility in the timing of expert depositions specifically addressed Nostrum's concerns, i.e., avoiding the wasting of time and money on experts which, in Nostrum's view, were not needed to resolve this case.

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B. THE APRIL 27, 2005 STATUS CONFERENCE

This Court held another Status Conference on April 27, 2005, during which the scheduling of expert depositions was revisited. Since no expert depositions yet had occurred, the Court once again ordered that expert deposition discovery *may* commence. *See* Order dated May 16, 2005 at 2 (emphasis added) (**Exhibit 2**).

During the April 27th Status Conference, the Court also scheduled oral argument on Nostrum's summary judgment motion for May 31, 2005. Due to scheduling conflicts, Shire's counsel requested that the hearing be adjourned to a later date. For Nostrum to consent to that adjournment, Shire had to agree not to take the depositions of Nostrum's experts until after the hearing so that Nostrum did not incur the expense of preparing and defending these witnesses. Similarly, Nostrum had no intention of deposing Shire's experts at that time. For all intents and purposes, expert discovery was stayed until the Court ruled on Nostrum's summary judgment motion.

**C. THE HEARING ON JULY 15, 2005 ON NOSTRUM'S
SUMMARY JUDGMENT MOTION**

On July 15, 2005, Judge Cooper heard oral argument on Nostrum's motion for summary judgment of noninfringement. In the course of preparation for this oral argument Shire identified, for the first time, a document in Nostrum's production that shows, through the use of a sieve analysis, that Nostrum's product contains three physically distinct units (the "sieve analysis"). The sieve analysis is particularly relevant to Shire's theory of infringement (but only if the Court were to accept Nostrum's claim construction).¹

Upon discovery of the sieve analysis, Shire immediately notified the Court and Nostrum that it intended, if the Court so permitted, to rely upon the document in opposing Nostrum's summary judgment motion of noninfringement. *See* Ltr. from S. Kuzmich to J. Cooper, 7/14/05 (**Exhibit 3**). As such, during the hearing Shire argued that if the Court were to adopt Nostrum's claim construction, summary judgment was not proper because, *inter alia*, an issue of material fact would remain as to whether Nostrum literally infringes given the disclosure in the sieve analysis. *See* July 15, 2005 Hearing Tr. at 142 (**Exhibit 4**).

¹ Nostrum's claim construction requires the patent claims to contain three physically distinct units. Additional expert discovery regarding the sieve analysis would be relevant only if the Court were to adopt *Nostrum's* claim construction, an interpretation that Shire strongly disputes.

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The Court denied Nostrum's summary judgment motion of noninfringement for a number of reasons. First, the Court decided that a *Markman* hearing, including expert testimony, would be necessary to construe the claims of the patent in issue. *See id.* at 146. Additionally, however, the Court determined that even if it were to adopt Nostrum's claim construction, there are "a myriad of questions concerning whether there is literal infringement . . ." *Id.* More to the point, the Court recognized the need for expert testimony on this very issue: "And you would need expert testimony, it seems to me, on the issue of literal infringement." *Id.* at 147.

Due to the identification of the sieve analysis just prior to the July 15th hearing, none of the experts had the opportunity to consider or address the issues raised by the sieve analysis in their reports. However, given the current schedule in the case, limited supplemental expert discovery on this important issue would not result in any duplication of effort or alteration in any projected Court dates.

For example, since expert depositions have still not begin, no expert would need to be re-deposed to obtain opinions on Shire's proposed supplemental expert discovery. Furthermore, your Honor informed the parties that the earliest possible date for a *Markman* hearing in this case is **January 2006**. Therefore, over the course of the next **five months**, there is more than sufficient time for the parties to exchange supplemental expert reports on issues raised by the sieve analysis and conclude expert deposition discovery prior to a *Markman* hearing (even assuming the Court's schedule permitted the hearing to be held in January, but might be later).

Shire anticipates that the supplemental expert discovery on the sieve analysis would involve the testing of Nostrum's product to determine: (1) whether three physically distinct pellet sizes exist in Nostrum's product; and (2) how the pellets of different sizes release carbamazepine. In other words, the supplemental expert discovery proposed by Shire is narrowly tailored and discrete. To preclude Shire from now taking additional, limited expert discovery on what is a literal infringement theory under Nostrum's claim construction results in extreme prejudice to Shire. Preclusion would be a drastic remedy given that the requested expert discovery would occur at a time when expert discovery is still ongoing and would cause no duplication of effort and no delay in the resolution of the litigation (i.e., a *Markman* hearing or trial).

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**D. SHIRE HAS GOOD CAUSE TO REQUEST
ADDITIONAL SUPPLEMENTAL EXPERT REPORTS**

Under Federal Rule of Civil Procedure 16(b), a court schedule “shall not be modified except upon a showing of good cause and by leave of the district judge or, when authorized by local rule, by a magistrate judge.” A finding of good cause depends on the diligence of the moving party. *See Globespanvirata, Inc. v. Texas Instruments Inc.*, No. Civ. A. 03-2854, 2005 WL 1638136, slip op., at *3 (D.N.J. July 12, 2005) (Hughes, J.).

Shire has good cause to seek supplemental expert reports regarding the sieve analysis issue:

First, Shire has diligently proceeded through discovery in this case. In fact, as the procedural history discussed above explains, it was Nostrum, not Shire, that consistently attempted to avoid and delay expert discovery.

Second, upon discovery of Nostrum’s sieve analysis document, Shire immediately and diligently disclosed the information to the Court and to Nostrum. In doing so, Shire explained that the Nostrum document may demonstrate that Nostrum’s product literally infringes the patent in suit even under Nostrum’s claim construction. *See* Ltr. from S. Kuzmich to J. Cooper, 7/14/05 (**Exhibit 3**).

Third, good cause also exists based upon the procedural posture of this case. Expert discovery has not yet concluded. In other words, there is still time for Shire’s proposed additional limited expert discovery to be accomplished before expert discovery closes and before the earliest possible date of a *Markman* hearing—January 2006.

Additionally, a Status Conference is scheduled for October 19, 2005 at which the final pretrial conference date would be set. Depending on the timely resolution of this immediate dispute, Shire could be in a position to submit its supplemental reports before this Status Conference, wait for Nostrum’s replies to the reports, and then offer its experts for deposition without disruption to the possible scheduling of a *Markman* hearing in early 2006.

Fourth, as also referenced above, during the course of the summary judgment hearing, Judge Cooper identified the need for expert discovery on the issue of literal infringement: “And you would need expert testimony, it seems to me, on the issue of literal infringement.” July 15, 2005 Hearing Tr. at 147 (**Exhibit 4**). Shire is attempting to meet the interests and needs expressed by Judge Cooper as well as to vindicate its own

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best interests by attempting to present a full record “on the issue of literal infringement.”²

Development of the sieve analysis issue is crucial, not only to protect Shire’s interests, but also: (1) to further the administration of justice; (2) to ensure that the trier of fact is provided with all of the relevant information so that a fair and proper decision can be rendered; and (3) to avoid a potential reversal on appeal for failing to explore the relevant information when available to the Court. Nostrum’s effort to ensure that the sieve analysis expert discovery is excluded is simply contrary to the administration of justice.

Fifth, this Court has recognized that courts should exercise particular restraint in excluding evidence. *See In re Mercedes-Benz Anti-Trust Litigation*, 225 F.R.D. 498, 504 (D.N.J. 2005). “The Third Circuit has, on several occasions, manifested a distinct aversion to the exclusion of important testimony absent evidence of extreme neglect or bad faith on the part of the proponent of the testimony.” *Id.* at 504-05, citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994); *see also Meyers v. Pennypack Woods Home Ownership Assoc.*, 559 F.2d 894, 905-06 (3rd Cir. 1977) (district court abused its discretion excluding witnesses when there was no bad faith and less drastic sanction of discovery with costs taxed to proponent of discovery was available).

Neither extreme neglect nor bad faith can be attributed to Shire in this litigation. Shire’s counsel moved expeditiously once it located the sieve analysis document to fulfill its obligation to its client Shire and the Court by disclosing same and seeking to explore and test its contents. Expert testimony on the sieve analysis can only serve the best interests of the parties and the Court in the interests of justice.

Under the present circumstances, substantial good cause exists to support Shire’s requested modification of the Scheduling Order.

E. THE PREJUDICE TO SHIRE IF SUPPLEMENTAL REPORTS ARE NOT ALLOWED AND THE OVERALL INTERESTS OF JUSTICE FAVOR ALLOWING SUPPLEMENTAL EXPERT REPORTS

Although the lack of prejudice to the non-movant does not show good cause, *see Globespanvirata*, 2005 WL 1638136, at *3, in this case Shire would be prejudiced and the interests of justice would not be served if the Court were to deny this application.

² Shire does so in order to protect its position in the event that the Court accepts Nostrum’s claim interpretation.

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See Dippel v. Farrell Lines Inc., No. 03 Civ. 130, 2004 WL 369140, at *1 (S.D.N.Y. Feb. 27, 2004) (although the expert disclosure failed to comply with the Case Management Plan, the interests of justice were best served by admitting the discovery even if it causes a minor delay in proceedings). “The Court in making such a determination must balance the need for doing justice on the merits between the parties (in spite of the oversights of their attorneys) against the need for maintaining orderly and efficient procedural arrangements.” *Id.*

Exclusion of the sieve analysis would have severe prejudicial effects on Shire. Shire has the burden to prove infringement, and the importance of this additionally limited discovery cannot be understated or ignored. Nostrum has consistently maintained throughout this litigation that its formulation uses “a single type of uncoated substantially homogenous bead containing carbamazepine dispersed throughout the bead.” *See* Nostrum’s Statement of Undisputed Material Facts submitted to this Court with Nostrum’s Motion for Summary Judgment, ¶¶ 4-5, December 10, 2004 (**Exhibit 5**). The sieve analysis reflects that, in fact, the beads in Nostrum’s product are not a single physical type—a fact which has tremendous consequences for Shire’s case if the Court were to accept Nostrum’s claim construction.

Additionally, Nostrum has plenty of recourse to deal with supplemental expert reports should this Court allow them. Because no expert depositions have occurred, Nostrum could reply to Shire’s supplemental expert reports and then depose, *for the first time*, Shire’s experts on all issues, including the sieve analysis.

The interests of justice would also be served by the supplemental expert discovery on the sieve analysis. First, Shire did not act in bad faith in its belated discovery of the sieve analysis. It immediately attempted to mitigate the timing of its discovery by full disclosure to both Nostrum and the Court. Second, Shire is not proposing to alter expert opinions already submitted on its behalf. Neither Shire nor its experts are changing proposed claim construction or revising theories of infringement. Instead, based on the identification of factual data on a very narrow issue, Shire is requesting permission to supplement its existing expert reports on a discretely defined topic—the sieve analysis. Third, as argued above, allowing the sieve analysis expert evidence allows the Court to thoroughly review the infringement issues upon a full factual and expert record before reaching a decision.

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CONCLUSION

We respectfully request oral argument on this application at a time to be set by the Court. We thank the Court for its consideration in this matter.

Respectfully submitted,

A handwritten signature in cursive script, reading "Arnold B. Calmann", with a circular stamp or mark to the right.

Arnold B. Calmann
Dennis E. Kadian
SAIBER SCHLESINGER SATZ & GOLDSTEIN, LLC
One Gateway Center, 13th Floor
Newark, New Jersey 07102
(973) 622-3333

Of Counsel:
Edgar H. Haug
Steven M. Amundson
Sandra Kuzmich
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800
Attorneys for Plaintiff
Shire Laboratories Inc.

Enclosures

cc: Gregory D. Miller, Esq. (via electronic mail)
Mark E. Waddell, Esq. (via electronic mail)
Sandra Kuzmich, Esq. (via electronic mail)